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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1985

ORTHO PHARMACEUTICAL CORPORATION,
*Petitioner,*

—v.—

CAROLE MACDONALD and BRUCE MACDONALD,
*Respondents.*

## PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT OF THE COMMONWEALTH OF MASSACHUSETTS

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August 29, 1985

## QUESTION PRESENTED

May an appeals court constitutionally fashion a new rule of substantive law through *de novo* fictional findings of fact made without affording the affected party an opportunity to be heard?

## LIST OF PARTIES TO THE APPEAL IN THE SUPREME JUDICIAL COURT OF THE COMMONWEALTH OF MASSACHUSETTS

The names of all of the parties to the appeal in the Supreme Judicial Court of the Commonwealth of Massachusetts are provided in the caption to this petition. Sup. Ct. R. 21.1(b). Ortho Pharmaceutical Corporation is a wholly owned subsidiary of Johnson & Johnson. Pursuant to Rule 28.1, the following are all of the affiliates of Johnson & Johnson, other than wholly owned subsidiaries:

ens Biologicals, Inc.

Enzo Biochem, Inc.

Immunomedics, Inc.

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## PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT OF THE COMMONWEALTH OF MASSACHUSETTS

Petitioner Ortho Pharmaceutical Corporation ("Ortho") respectfully requests that a Writ of Certiorari issue to review the judgment of the Supreme Judicial Court of the Commonwealth of Massachusetts entered on February 28, 1985.

## PRIOR OPINIONS

The opinion of the Supreme Judicial Court of Massachusetts reversing the trial court was issued on February 28, 1985, is reported at 394 Mass. 131, 475 N.E.2d 65 (1985), and is reprinted in the Appendix at pages 1a-17a. The judgment of the Supreme Judicial Court is reprinted at page 22a, and the order denying Ortho's Petition for Rehearing was issued on April 1, 1985 and is reprinted at pages 23a-24a. The decision of the Superior Court granting Ortho's motion for judgment notwithstanding the verdict was issued on July 29, 1983 and is reprinted at pages 18a-21a. The judgment of the Superior

Court was issued on August 1, 1983 and is reprinted at page 25a. The jury's special interrogatory responses are reprinted at pages 26a-27a.

## JURISDICTION

The opinion of the Supreme Judicial Court reinstating the jury's verdict against Ortho was filed on February 28, 1985. The mandate of the Supreme Judicial Court issued on April 1, 1985, following the denial on that date of Ortho's Petition for Rehearing. By order dated June 17, 1985, Justice William J. Brennan, Jr. extended the time for filing a petition for a writ of certiorari to and including August 29, 1985. This Court has jurisdiction to review the judgment of the Supreme Judicial Court of the Commonwealth of Massachusetts by writ of certiorari pursuant to 28 U.S.C. § 1257(3).

## CONSTITUTIONAL PROVISIONS INVOLVED

This case involves the following constitutional provision, the text of which is reprinted at page 28a:

— U.S. Const. amend XIV, § 1 (*Due Process Clause*)

## STATEMENT OF CASE

Until the instant case, the unanimous nationwide appellate authority had held that the duty to warn about the side effects of all prescription drugs, including oral contraceptives ("o.c.'s"), was to the prescriber rather than to the patient. In the decision below, however, the Supreme Judicial Court of Massachusetts invented *ab initio* judicial findings of fact differentiating between o.c.'s and other prescription drugs and used these findings to justify the creation of a new rule of law requiring o.c. sellers to warn patients directly of side effects. Most of these findings are contrary to actual fact. The court then held that in this case the o.c. seller violated the newly

created duty to warn o.c. patients. It did so even though Ortho had in fact issued patient warnings that complied with the applicable regulations of the United States Food and Drug Administration ("FDA"), were written in the precise lay language mandated by the FDA, and warned of the precise side effect suffered by respondent.

As the dissent below correctly noted, the court "assume[d] facts not established on the record" to reach its startling decision. *MacDonald v. Ortho Pharmaceutical Corp.*, *supra*, 394 Mass. at 147, 475 N.E.2d at 74, App. at 16a. In so doing, the lower court violated one of a litigant's most basic constitutional rights—the right to be heard. By relying upon non-record facts conceived during the appellate process, the lower court ignored long-standing due process limitations on judicial notice. Moreover, it compounded these due process violations by failing to place Ortho on notice that the court would engage in such *ex parte* fact finding. Such judicial conduct violates basic precepts of due process and contravenes prior holdings of this Court. Because of the tremendous expansion of liability inherent in this unconstitutionally created new rule of law, the decision should not stand.

## STATEMENT OF FACTS

In September 1973 respondent Carole MacDonald (Ms. MacDonald) visited her gynecologist and inquired about obtaining an effective form of contraception. At that time, her physician prescribed Ortho Novum, a brand of o.c.'s sold by Ortho. Along with the prescription, Ms. MacDonald obtained from her gynecologist a patient brochure prepared by Ortho which described the side effects of o.c.'s. Ortho prepared this brochure in accordance with applicable FDA regulations and distributed it to prescribing physicians who could, in their discretion, give it to their patients. The booklet contained detailed information about the side effects of o.c.'s, including the fact that there is an increased risk to o.c. users of abnormal blood clotting that "may threaten life" if the blood clots

"break loose . . . or if they form in other vital organs, such as the brain."

Ms. MacDonald began taking Ortho Novum tablets following the September 1973 visit to her gynecologist. Ortho Novum was sold by prescription only. Ms. MacDonald's prescription called for her to receive one dispenser of the drug each month. Each of these dispensers was labeled according to FDA directives and contained the explicit warning that "oral contraceptives are powerful and effective drugs which can cause side effects in some women. . . . The most serious known side effect is abnormal blood clotting which can be fatal." The FDA regulation in question required that all oral contraceptive manufacturers use this precise wording on the drug dispensers. It also established the substance of the warning to be used in the patient information brochure. 35 Fed. Reg. 9001-03 (1970).

Ms. MacDonald renewed her prescription for Ortho Novum pills at subsequent annual visits to her gynecologist. On July 24, 1976, after using the pills for approximately three years, Ms. MacDonald suffered a blood clot in a cerebral artery which resulted in her permanent partial disablement.

## PROCEEDINGS BELOW

Ms. MacDonald and her husband filed suit in the Superior Court against Ortho seeking recovery for personal injuries. The case was submitted to the jury on a special verdict form which included the following interrogatories: (1) was Ms. MacDonald's injury caused by o.c.'s? (2) was Ortho negligent in its warnings to the prescribing physician? (3) was Ortho negligent in its failure to warn Ms. MacDonald? (4) was Ortho's negligence in its warning to Ms. MacDonald the cause of her injuries? The jury found that Ortho had adequately warned Ms. MacDonald's prescribing physician of the dangers of o.c.'s, but had not adequately warned her of such dangers and that these inadequate patient warnings caused her injuries. It awarded $800,000 to Ms. MacDonald and $50,000 to Mr. MacDonald. App. at 26a-27a.

On July 29, 1983, the trial court granted Ortho's motion for judgment notwithstanding the verdict. The court held that it was Ortho's duty to warn only the prescribing physician. "[B]ecause the jury found that [Ortho] adequately warned the plaintiff's physician", the court held that Ortho was entitled to judgment as a matter of law. App. at 21a.

The Supreme Judicial Court reversed. It acknowledged that "in cases involving prescription drugs [the rule] is that the prescribing physician acts as a 'learned intermediary' between the manufacturer and the patient, and 'the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient,' " *MacDonald v. Ortho Pharmaceutical Corp.*, *supra*, 394 Mass. at 136, 475 N.E.2d at 69, App. at 6a (quoting *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 386-87, 528 P.2d 522, 529 (1974)), but concluded that o.c.'s "bear peculiar characteristics that warrant the imposition of a common law duty on the manufacturers to warn users directly of associated risks." *Id.* at 136-37, 475 N.E.2d at 69, App. at 6a. The court proceeded to make up these peculiar characteristics. In so doing, it cited no evidence in the record to support its conclusion that o.c.'s are somehow peculiar among prescription drugs. No such evidence exists in the record or in the real world.

Once the lower court created the new common law duty to warn patients directly, it concluded that the evidence supported the jury's finding that Ortho had breached the duty. According to the court, the jury could have found Ortho negligent because Ortho used the FDA-mandated phrase "abnormal blood clotting which can be fatal" rather than the term "strokes". 394 Mass. at 141, 475 N.E.2d at 71-72, App. at 11a.[1] According to the court, the jury was free to decide that

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1 The term "abnormal blood clotting" includes, of course, not only occlusion of blood vessels in the head, *i.e.*, strokes, but also occlusion of vessels in the heart, *i.e.*, myocardial infarcts (heart attacks), occlusion of vessels in the lungs, *i.e.* pulmonary emboli (lung failures), and blockage of veins throughout the peripheral vascular system, but most commonly in the legs due to venous pooling, *i.e.* thrombophlebitis (sore or swollen legs).

the failure to use the work "stroke" rendered the warning inadequate and that "there are fates worse than death, such as . . . permanent disablement" so that even a warning about death was not sufficient to warn the consumer adequately. *Id.*

By timely petition for rehearing, Ortho first challenged the constitutionality of the process by which the Supreme Judicial Court reached its decision. Ortho claimed that the court's appellate fact-finding and reliance upon non-record evidence to impose liability upon Ortho contravened Ortho's rights under the Fourteenth Amendment to due process of law. The Supreme Judicial Court, however, denied Ortho's petition for rehearing without comment. App. at 23a-24a.

## REASONS WHY THE WRIT SHOULD BE GRANTED

This case trailblazes new law in one of the most important areas in the field of torts—the prescription drug liability field. The way the lower court reached this new ground warrants intervention by this Court. The new rule of law was adopted on the basis of fictive findings of fact which Ortho was never allowed to test. Thus, the decision below is in direct conflict with this Court's clear holding in *Ohio Bell Telephone Co. v. Public Utilities Commission*, 301 U.S. 292 (1937). Allowing the decision to pass unreviewed will destroy any semblance of stability in the important area of tort law and will deprive Ortho of its fundamental right to be heard.

## I. THE LOWER COURT'S RELIANCE UPON ASSERTED "FACTS" OUTSIDE THE RECORD TO JUSTIFY AN UNPRECEDENTED THEORY OF LIABILITY OFFENDS DUE PROCESS

"The fundamental requisite of due process of law is the opportunity to be heard", *Grannis v. Ordean*, 234 U.S. 385, 394 (1914), and this opportunity "must be granted at a meaningful time and in a meaningful manner", *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). *Accord*, *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428-29 (1982); *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971). Due process requires that a party also be accorded meaningful notice before his rights are the subject of adjudication. *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313-14 (1950).

The decision below deprived Ortho of each of these essential elements of due process. At no time did the court place Ortho on notice that it would review the "peculiar" nature of oral contraceptives or the scope of FDA regulation over patient labeling. Nor did the court ever suggest that it would engage in any fact finding at all, which is traditionally the province of the trial court. Similarly, by turning the appellate process into a *de novo* and *ex parte* fact-finding inquiry, the lower court effectively stripped Ortho of an opportunity to be heard in opposition to the factually unsound findings made by the court regarding o.c's.

***Oral Contraceptives Are Not Unique Among Prescription Drugs.*** The lower court purported to base its deviation from all prior prescription drug law on the basis of certain supposed facts that set o.c.'s apart from all other prescription drugs. According to the Court, the following six findings establish the "peculiar characteristics" that distinguish o.c.'s from other prescription drugs:

1) "the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use 'the pill,' as opposed to other available birth control prod-

ucts, and the prescribing physician is relegated to a relatively passive role" (App. at 6a);

2) "the physician prescribing 'the pill,' as a matter of course, examines the patient once before prescribing an oral contraceptive and only annually thereafter" (App. at 6a);

3) "the birth control pill is specifically subject to extensive Federal regulation", including requirements that specific warnings be provided directly to patients (App. at 7a);

4) there are "substantial risks affiliated with the product's use" (App. at 8a);

5) there exists "the feasibility of direct warnings by the manufacturer to the user" (App. at 8a); and

6) there exists "the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers" (App. at 8a).

These findings have no basis in the record. Moreover, they are either contrary to actual fact or are characteristics that do not set o.c.'s apart from other prescription drugs. If Ortho had been given the opportunity to make a record on these points, it would have established that each of these six findings was either erroneous or a characteristic shared by many other prescription drugs.

Perhaps the most egregious of these "findings" is the lower court's conclusion that prescribing physicians are "relegated to a relatively passive role" in the determination whether to use oral contraceptives or some other form of birth control.[2] As

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2 The text of this petition discusses the nature of the presentation that Ortho would have made at a plenary evidentiary hearing with respect to only one of the six supposed facts that make oral contraceptives unique among prescription drugs. The remaining five "facts" cited by the lower court would be shown to be equally erroneous were Ortho given an opportunity to present

stated at the very page of D. Danforth, *Obstetrics and Gynecology* (4th ed. 1982), relied on by the lower court (App. at 6a-7a):

> When prescribing oral contraceptives, the physician *must* weigh the benefits against the risks for the individual patient.
>
> * * *
>
> Before [o.c.] therapy is initiated, as well as during these checkups, a pelvic examination should be performed and the patient's blood pressure and weight should be recorded. A breast examination and palpation of the right upper quadrant of the abdomen should also be performed. In women less than 35 years of age, 2-hour postprandial blood glucose should be obtained if there is a family history of diabetes mellitus or prior unexplained stillbirth. Liver function tests should be performed in women with a past history of liver disease. If either of the patient's parents suffered a myocardial infarction before the age of 65, a lipid profile should be obtained. In all women over 35 who use oral contraception, 2-hour postprandial blood glucose and lipid profile should be measured annually. If any of these tests is abnormal,

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evidence. For instance, all prescription drugs are subject to extensive Federal regulation, and the FDA requires patient warnings to be given in connection with a number of other drugs and medical devices. *E.g.*, 21 C.F.R. § 310.515 (estrogen products); 21 C.F.R. § 310.516 (progestational products); 21 C.F.R. § 201.305 (isoproterenol products); 21 C.F.R. 310.502 (intrauterine devices); *see also* 45 Fed. Reg. 60,754-817 (1980) (evaluating proposed patient labeling for numerous other prescription products). This Court may take judicial notice of the contents of both the Code of Federal Regulations and the Federal Register. 44 U.S.C. §§ 1507, 1510.

In addition, oral contraceptives are not uniquely prescribed for up to one year intervals. Dozens of drugs are prescribed on comparable regimens, such as antihypertensive agents, oral hypoglycemics, or drugs for chronic stomach or heart ailments. Needless to say, the possibility that the time gap between prescriptions increases the risk of forgetting warnings for all of these drugs. Finally, the feasibility of providing direct patient warnings is, on its face, the same for all orally ingested drugs.

another method of contraception should be used. (Emphasis added.)

Prescription of few pharmaceutical agents is preceded by such rigorous examination and testing. Indeed, as the AMA stated in connection with the distribution of the FDA-mandated patient labeling to doctors in 1970, the goal of providing any information about oral contraceptives directly to the patient was to "reinforce the role of the physician as the best source of patient information."[3]

Moreover, Ortho would prove at a hearing that the patient must—and does—rely upon her physician in determining the method of contraception. It can be shown that the use of oral contraceptives as opposed to other forms of birth control involves precisely the same kind of balancing of benefits against risks that goes into all decisions regarding the prescription of a drug. For instance, it is the physician who is best able to determine whether the patient falls in the class of women who are at high risk if exposed to oral contraceptives. Similarly, there are women for whom pregnancy presents serious health risks, including death. O.c.'s are unique among the various reversible methods of contraception in that they are almost 100 percent effective if used as directed, so the physician is in the best position to judge the necessity of taking the most effective contraceptive measures possible. Indeed, physicians often prescribe these agents for the dual purposes of contraception and therapy (*e.g.*, hypermenorrhea).

It can also be demonstrated that the physician is in the best possible position to deliver *effective* warnings to the patient. Studies that have been performed reveal that direct warnings by physicians—as is envisioned by the standard rule that the drug manufacturer must warn the physician—are more likely to be understood by patients than are warnings contained in

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3 Letter from Walter C. Bornemeier, M.D., President of the American Medical Association, to the Medical Community, dated August 17, 1970 (App. at 29a-30a).

printed materials issued by drug companies and read, if at all, after the decision to go on an oral contraceptive regimen has been made.

At least one court has already explicitly rejected the "facts" as found by the Massachusetts court. *See Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, 203, 423 N.E.2d 831, 840 (1981) (the physician plays a critical role in the decision to use oral contraceptives). Numerous other courts have rejected *sub silentio* the notion that oral contraceptives are unique among prescription drugs. *See, e.g., Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 400 (1971). While these authorities may not be dispositive of whether oral contraceptives are, in fact, unique prescription drugs, they reflect the obvious point that the issue is one of fact as to which reasonable minds might differ. Consequently, the lower court could not, consistent with the due process, adjudicate this issue without the receipt of evidence.

***The FDA Controls Oral Contraceptive Labeling.*** The lower court's factual assumptions about the extent of FDA regulations concerning direct patient labeling are also wrong and would be disproved by Ortho if it is given the opportunity. In particular, the court below created and then relied upon a mistaken assumption that the FDA only sets minimum standards for the content of the warnings it requires, which the drug manufacturer may fine tune or to which it may add more warnings as it sees fit. The FDA does not play such a passive role in labeling and, as the dissent below correctly pointed out, the FDA has mandated the exact language that may be employed in the patient warning materials distributed with oral contraceptives. 394 Mass. at 147, 475 N.E.2d at 75, App. at 17a.

This is merely one example of the FDA's use of its power to issue regulations governing the content of labeling of prescription drugs. 21 U.S.C. § 352(a). By law it must regulate the provision of information regarding the "side effects, contraindications and effectiveness" of prescription drugs. 21 U.S.C.

§ 352(n). As part of its duty to see that the labeling "omits no information pertinent to the safe and effective prescribing of the drug by the physician", 37 Fed. Reg. 16,503-04 (1972), the FDA not only regulates what is in the package insert, but more important for purposes of this case what is *not* to be in the package insert. The FDA made this power explicit after it was enjoined from requiring the listing as a side effect in the inserts for anti-diabetic drugs certain alleged but unproven cardiovascular adverse reactions. *See Bradley v. Weinberger*, 483 F.2d 410, 416-17 (1st Cir. 1973); 21 C.F.R. § 1.21; 39 Fed. Reg. 33,229-32 (1974).

In connection with the oral contraceptive patient labeling, the FDA has specifically required the exact language used by Ortho in its warnings on the o.c. drug container. The relevant regulation required Ortho to state in its warnings that the "most serious known side effect is abnormal blood clotting which can be fatal." 21 C.F.R. § 130.45(d)(1) (1970), recodified at 21 C.F.R. § 310.501(a)(6) (1974); *see also* 35 Fed. Reg. 9002-03 (1970).

Thus, the FDA regulates not only what the patient labeling shall contain (a minimum, passive role) but also how the messages are to be communicated to the patient and what shall *not* be placed in the labeling (an active, supervisory role). Proof of this active role consists not only of interpretation of the relevant regulations, but also of custom and practice. Proof of the pervasive role of the FDA over patient labeling content is critical not only to this case but to all of the hundreds of prescription drug liability cases. The same sort of "findings" made by the lower court here can be made with respect to virtually any oral drug taken on a regular or when-needed basis. Due process, however, requires that drug companies be given at least one opportunity to demonstrate the true state of facts surrounding the role of the FDA in patient labeling before a court may impose liability on the basis of its assumptions about that role.

***The Court's Decisional Process Violated Due Process.*** The court below thus committed constitutional error in expanding liability under a new and vitally important rule of law on the basis of factual assumptions that have no evidentiary foundation. Moreover, the lower court's decision can only spur other courts into adopting the same unprincipled findings pursuant to *stare decisis*. Indeed, one court has already interpreted the lower court's decision as indicating that the "resistance to change has been broken" and has adopted the same factual assumptions in lieu of hearing evidence on the point. *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867, 879 (E.D. Mich. 1985). At least one other court has also based its decision upon the same factual assumptions, utilizing the same reasoning and extra-record fact-finding process as the Massachusetts court to deny a drug company the opportunity to demonstrate that o.c.'s are not unique prescription drugs requiring special legal treatment. *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380-81 (E.D. Mich. 1985). It is a firm tenet of law, however, that a court, trial or appellate, may not consider information not admitted into evidence when reaching a decision in a particular case, *see United States v. Standard Oil Co.*, 618 F.2d 511, 519-20 (9th Cir. 1980); *Warner v. Kewanee Machinery & Conveyor Co.*, 411 F.2d 1060, 1065-66 (6th Cir. 1969), *cert. denied*, 398 U.S. 906 (1970), and that "a judgment supported by no evidence on an essential element violates due process", *In re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238, 304 n.55 (3d Cir. 1983), *cert. granted sub nom. Matsushita Electrical Industrial Co. v. Zenith Radio Corp.*, ____ U.S. ____, 105 S. Ct. 1863 (1985). *Accord*, *Vachon v. New Hampshire*, 414 U.S. 478, 480 (1974); *Johnson v. Florida*, 391 U.S. 596, 598 (1968); *Thompson v. Louisville*, 362 U.S. 199, 206 (1960).

Indeed, precisely the sort of judicial conduct engaged in here has been held to violate the Due Process Clause. In *Ohio Bell Telephone Co. v. Public Utilities Commission*, 301 U.S. 292 (1937), this Court voided on due process grounds certain actions taken by an administrative agency that were based on extra-record evidence, stating that "[t]he fundamentals of a

trial were denied appellant when rates previously collected were ordered to be refunded upon the strength of evidential facts not spread upon the record." *Id.* at 300. The Court added that "[t]his is not the fair hearing essential to due process. It is condemnation without trial." *Id.*

Similarly, in *Saunders v. Shaw*, 244 U.S. 317 (1917), the Supreme Court struck down a decision of the Louisiana Supreme Court that had granted an injunction on the basis of evidence that had been ruled inadmissible.[4] According to the Court, due process required that the defendant be granted an opportunity to rebut the non-record evidence that the lower court had deemed material.[5] Due process similarly requires that Ortho be given a chance to rebut non-record evidence that the court below has deemed material.

* * *

The lower court's decision was reached at a time of great upheaval in the law of products liability. The public is becom-

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4 *Accord, Willner v. Committee on Character & Fitness*, 373 U.S. 96, 105 (1963) (decision that may have been based upon nondisclosed written reports cannot withstand scrutiny under Due Process Clause); *In re Murchison*, 349 U.S. 133, 138-39 (1955) (denial of due process for judge to perform prosecutorial tasks because his decision will necessarily be infected by observations and evidence not placed in the record); *United States v. Abilene & Southern Ry.*, 265 U.S. 274, 288-90 (1924) (denial of due process to base order upon unintroduced evidence).

5 The lower court's use of these unsupported and unprovable findings about oral contraceptives cannot be justified on the basis of judicial notice. *Ohio Bell Telephone Co. v. P.U.C.*, 301 U.S. 292, 300-02 (1937) (*citing Shapleigh v. Mier*, 299 U.S. 468, 475 (1937)). A court may take judicial notice only of matters that are of "common knowledge". *Ross v. Gardner*, 365 F.2d 554, 557 (6th Cir. 1966); *Town of Nantucket v. Beinecke*, 379 Mass. 345, 352, 398 N.E.2d 458, 462 (1979); Fed. R. Evid. 201(b). As the Fifth Circuit has recently stated, "judicial notice applies to self-evident truths that no reasonable person could question, truisms that approach platitudes or banalities." *Hardy v. Johns-Manville Sales Corp.*, 681 F.2d 334, 347 (5th Cir. 1982) (rejecting argument that court could judicially notice that exposure to asbestos fibers can cause cancer).

ing increasingly aware that many of the results in this area are unjust and illogical and do not promote the primary objectives of encouraging safer products and the fair compensation of injured victims. Rather it operates as a part of medical lottery when a few plaintiffs' lawyers and a few plaintiffs get enormously rich and where at least two-thirds of all monies paid do not go to those suing. *See* S. Rep. No. 98-476, 98th Cong., 2d Sess. 7 (1984); Institute for Civil Justice of The Rand Corporation, *Cost of Asbestos Litigation* (July 1983). This illogic and lack of fairness engenders disrespect for the legal system. *See generally* Huber, *Safety and the Second Best: The Hazards of Risk Management in the Courts*, 85 Colum. L. Rev. 277 (1985); Henderson, *Product Liability and the Passage of Time: The Imprisonment of Corporate Rationality*, 58 N.Y.U.L. Rev. 765 (1983); Owen, *Punitive Damages in Products Liability Litigation*, 74 Mich. L. Rev. 1258 (1976). That disrespect can only increase where, as here, an appeals court indulges in fictional fact finding to justify a result-oriented decision.

There has been rapidly escalating concern that the lack of uniformity and certainty in this area of the law has caused such economic dislocation as the filing for bankruptcy by solvent corporations,[6] the unavailability of risk-spreading insurance,[7]

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6 *See, e.g., In re UNR Industries, Inc.*, Nos. 82-B-9841 to 82-B-9851 (Bankr. N.D. Ill. filed July 29, 1982); *In re Johns-Manville Corp.*, Nos. 82-B-11,656 to 82-B-11,676 (Bankr. S.D.N.Y. filed Aug. 26, 1982); *In re Amatex Corp.*, No. 82-05220k (Bankr. E.D. Pa. filed Nov. 1, 1982); *In re Aquaslide'n'Dive Corp.*, No. LA-84-23505 (Bankr. C.D. Cal. filed Dec. 7, 1984); *In re A.H. Robins Co.*, No. 85-013-07-R (Bankr. E.D. Va. filed Aug. 21, 1985). *See generally* Note, *Relief from Tort Liability through Reorganization*, 131 U. Pa. L. Rev. 1227 (1983).

7 *See, e.g.*, Brief of Home Ins. Co., Amicus Curiae, at 11n., *American Home Products Corp. v. Liberty Mutual Ins. Co.*, Nos. 83-7952, 7990 (2d Cir. March 8, 1984) ("insurers may exclude from coverage risks associated with certain products after such products' hazards become generally known. Such was the case with losses relating to DES injury, which have been routinely excluded from policies issued after 1975."); N.Y. Times, *Insurance Problems Hinder Asbestos Removal at Schools*, at A14, col. 3 (April 22, 1985).

and the withdrawal of vital products from the market.[8] *See generally Product Liability Reform: Hearings on S. 2631 Before the Subcomm. for Consumers of the Comm. on Commerce, Science, and Transportation*, 97th Cong., 2d Sess. (1982); *To Regulate Interstate Commerce by Providing for a Uniform Product Liability Law: Hearings on S. 44 Before the Subcomm. on the Consumer of the Comm. of Commerce, Science, and Transportation*, 98th Cong., 1st Sess. (1983). One consequence of this upheaval is gathering support for federal preemption of state products liability law, the aim of which is to reduce the burdens on interstate commerce occasioned by "the current climate of uncertainty in product liability law . . . [and to] achiev[e] uniformity among State and Federal courts." S. Rep. No. 98-476, 98th Cong., 2d Sess. 10 (1984).[9]

The decision below is typical of the discriminatory treatment of drug companies in an ever increasing number of jurisdictions. *Cf. Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 565-66 (7th Cir. 1984) ("there are many Americans who find drug companies in general to be objects they love to hate. . . . It was the same way with railroads a century ago, and no doubt there will be some new unforeseen scapegoat for public

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8 *See, e.g.*, Swine Flu Program Act of 1976, Publ. L. No. 94-380, 90 Stat. 1113, codified at 42 U.S.C. § 247b(j)-(1) (1976); S. Rep. No. 94-1147, 94th Cong., 2d Sess. 1, reprinted in 1976 U.S. Code Cong. & Ad. News 1987; N.Y. Times, *Wyeth Vaccine*, at D4, col. 6 (June 20, 1984) (withdrawal of one of three whooping cough vaccine manufacturers from the market); N.Y. Times, *Maker of Vaccine Quits the Market*, at A21, col. 1 (Dec. 12, 1984) (withdrawal of second of three whooping cough vaccine manufacturers from the market). *See generally* 1984 Cong. Quarterly, *Concern in Congress: Looming Vaccine Shortage Blamed on Threats of Lawsuits*, at 3146 (Dec. 22, 1984); Business Week, *A Risky Exodus from Vaccines*, at 118-20 (April 10, 1978).

9 Senate Bill 44, which was the subject of S. Rep. 98-476, was reported to the full Senate in 1984, but was never considered by the full Senate. Several bills have been introduced in the Congress during the current session to achieve a uniform Federal law of product liability. *E.g.*, S. 100, H.R. 2568. S. 100 was considered by the Senate Commerce Committee but was not reported to the Senate. H.R. 2568 is still pending.

ire in A.D. 2084, at which time drug companies will be the objects of commiseration that railroads are today.") Appellate courts, however, cannot be allowed to make up new facts to justify expansion of liability. Although the lower court's extension of its state law may not in and of itself raise a substantial federal question, the irregular manner in which it adopted the new rule of law does raise important questions of Federal law. As this Court stated many years ago,

> "while it is for the state courts to determine the adjective as well as the substantive law of the State, they must, in so doing, accord the parties due process of law."

*Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 682 (1930).

Ortho is ready, willing, and able to offer evidence that will disprove the "factual" assumptions at the heart of the lower court's decision. If a plenary evidentiary hearing is held, Ortho will show that oral contraceptives are not unique prescription drugs and that the FDA fixes the actual content of labeling. The Due Process Clause requires that Ortho be given at least one chance to do so.

## CONCLUSION

For the reasons stated above, this Petition for a Writ of Certiorari to the Supreme Judicial Court of the Commonwealth of Massachusetts should be granted.

August 29, 1985

Respectfully submitted,

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# APPENDIX

**Opinion of the Supreme Judicial Court**

No. SJC-W-3489

CAROLE D. MACDONALD & another[1],

vs.

ORTHO PHARMACEUTICAL CORPORATION.

ABRAMS, J. This products liability action raises the question of the extent of a drug manufacturer's duty to warn consumers of dangers inherent in the use of oral contraceptives. The plaintiffs brought suit against the defendant, Ortho Pharmaceutical Corporation (Ortho), for injuries allegedly caused by Ortho's birth control pills, and obtained a jury verdict in their favor. The defendant moved for a judgment notwithstanding the verdict. The judge concluded that the defendant did not owe a duty to warn the plaintiffs, and entered judgment for Ortho. The plaintiffs appealed. We transferred the case to this court on our own motion and reinstate the jury verdict.[2]

We summarize the facts. In September, 1973, the plaintiff Carole D. MacDonald (MacDonald), who was twenty-six years old at the time, obtained from her gynecologist a prescription for Ortho-Novum contraceptive pills, manufactured by Ortho. As required by the then effective regulations promulgated by the United States Food and Drug Administration (FDA), the pill dispenser she received was labeled with a warning that "oral contraceptives are powerful and effective drugs which

1 The other plaintiff is Bruce MacDonald, Carole MacDonald's husband.

2 The only issues before us are issues of the drug manufacturer's liability.

can cause side effects in some users and should not be used at all by some women," and that "[t]he most serious known side effect is abnormal blood clotting which can be fatal."[3] The warning also referred MacDonald to a booklet which she obtained from her gynecologist, and which was distributed by Ortho pursuant to FDA requirements. The booklet contained detailed information about the contraceptive pill, including the increased risk to pill users that vital organs such as the brain may be damaged by abnormal blood clotting.[4] The word

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3 FDA regulations in effect during the time period relevant to this litigation required that the following warning be included in or with the pill dispenser:

> "Do Not Take This Drug Without Your Doctor's Continued Supervision.
>
> "The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.
>
> "Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, (Firm name) has prepared a booklet (or other form) written in a style understandable to you as the drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.
>
> "Notify your doctor if you notice any unusual physical disturbance or discomfort."

21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970), recodified at 21 C.F.R. § 310.501(a)(4), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5354 (1974).

4 Applicable FDA regulations required that the booklet contain "information in lay language, concerning effectiveness, contra-indications, warnings, precautions, and adverse reactions," including a warning "regarding the serious side effects with special attention to thromboembolic disorders and stating the estimated morbidity and mortality in users vs. nonusers." 21 C.F.R. § 130.45(e) & (e)(3), 35 Fed. Reg. 9002, 9003 (1970), recodified at 21 C.F.R. § 310.501(a)(6) & (a)(6)(iii), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5353 (1975). Ortho's booklet contained the following information:

> "About blood clots
>
> "Blood clots occasionally form in the blood vessels of the legs and the pelvis of apparently healthy people and may threaten life if the

"stroke" did not appear on the dispenser warning or in the booklet.

MacDonald's prescription for Ortho-Novum pills was renewed at subsequent annual visits to her gynecologist. The prescription was filled annually. On July 24, 1976, after approximately three years of using the pills, MacDonald suffered an occlusion of a cerebral artery by a blood clot, an injury commonly referred to as a stroke.[5] The injury caused the death of approximately twenty per cent of MacDonald's brain tissue, and left her permanently disabled. She and her husband initiated an action in the Superior Court against Ortho, seeking recovery for her personal injuries and his consequential damages and loss of consortium.

MacDonald testified that, during the time she used the pills, she was unaware that the risk of abnormal blood clotting encompassed the risk of stroke, and that she would not have used the pills had she been warned that stroke is an associated risk.[6] The case was submitted to a jury on the plaintiffs'

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clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain. It has been estimated that about one woman in 2,000 on the pill each year suffers a blood clotting disorder severe enough to require hospitalization. The estimated death rate from abnormal blood clotting in healthy women under 35 not taking the pill is 1 in 500,000; whereas for the same group taking the pill it is 1 in 66,000. For healthy women over 35 not taking the pill, the rate is 1 in 200,000 compared to 1 in 25,000 for pill users. Blood clots are about three times more likely to develop in women over the age of 34. For these reasons it is important that women who have had blood clots in the legs, lungs or brain not use oral contraceptives. Anyone using the pill who has severe leg or chest pains, coughs up blood, has difficulty breathing, sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness of an arm or leg, should call her doctor immediately and stop taking the pill."

5 MacDonald's hospital records refer to her injury as a "cerebral vascular accident," terminology likewise descriptive of brain damage attributable to blood clotting.

6 Subsequent to the events in this case, the FDA regulation was amended by 43 Fed. Reg. 4221 (1978), which replaced the regulation requirement of a specified warning on the pill dispenser, see note 3 *supra*,

theories that Ortho was negligent in failing to warn adequately of the dangers associated with the pills and that Ortho breached its warranty of merchantability. These two theories were treated, in effect, as a single claim of failure to warn. The jury returned a special verdict, finding no negligence or breach of warranty in the manufacture of the pills. The jury also found that Ortho adequately advised the gynecologist of the risks inherent in the pills;[7] the jury found, however, that Ortho was negligent and in breach of warranty because it failed to give MacDonald sufficient warning of such dangers. The jury further found that MacDonald's injury was caused by Ortho's pills, that the inadequacy of the warnings to MacDonald was the proximate cause of her injury, and that Ortho was liable to MacDonald and her husband.[8]

After the jury verdict, the judge granted Ortho's motion for judgment notwithstanding the verdict, concluding that, because oral contraceptives are prescription drugs, a manufacturer's duty to warn the consumer is satisfied if the manufacturer gives adequate warnings to the prescribing physician, and that the manufacturer has no duty to warn the consumer directly.

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with a requirement that the dispenser contain a warning "of the serious side effects of oral contraceptives, such as thrombophlebitis, pulmonary embolism, myocardial infarction, retinal artery thrombosis, *stroke*, benign hepatic adenomas, induction of fetal abnormalities, and gallbladder disease" (emphasis added). See 21 C.F.R. § 310.501(a) (2)(iv) (1984).

7 MacDonald stated at trial that her gynecologist had informed her only that oral contraceptives might cause bloating, and had not advised her of the increased risk of stroke associated with consumption of birth control pills. The physician was not joined as a defendant in this action, and no questions relating to any potential liability on his part are before us.

MacDonald further testified at trial that she had read both the warning on the Dialpak tablet dispenser as well as the booklet which she received from her gynecologist. See notes 3 and 4, *supra*.

8 The only issue before us concerns the scope of Ortho's duty to the plaintiffs. The defendant does not contest the damages but relies solely on its claim that it owes no duty to warn the plaintiffs directly.

The narrow issue, on appeal, is whether, as the plaintiffs contend, a manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill. We conclude that such a duty exists under the law of this Commonwealth.

1. *Extent of duty to warn.* Ordinarily, "a manufacturer of a product, which the manufacturer knows or should know is dangerous by nature or is in a dangerous condition," is under a duty to give warning of those dangers to "persons who it is foreseeable will come in contact with, and consequently be endangered by, that product." *H.P. Hood & Sons* v. *Ford Motor Co.*, 370 Mass. 69, 75 (1976). The element of privity being long discarded, a manufacturer's warning to the immediate purchaser will not, as a general matter, discharge this duty. However, "there are limits to that principle." *Carter* v. *Yardley & Co.*, 319 Mass. 92, 98 (1946). Thus, "a manufacturer may be absolved from blame because of a justified reliance upon . . . a middleman." *Id.* at 99. This exception is applicable only in the limited instances in which the manufacturer's reliance on an intermediary is reasonable. See Restatement (Second) of Torts § 388, comment n (1965). In such narrowly defined circumstances, the manufacturer's immunity from liability if the consumer does not receive the warning is explicable on the grounds that the intermediary's failure to warn is a superseding cause of the consumer's injury, or, alternatively, that, because it is unreasonable in such circumstances to expect the manufacturer to communicate with the consumer, the manufacturer has no duty directly to warn the consumer.[9] See generally 1A

9 Ortho points out that a number of courts have reached this result in oral contraceptive cases. See, e.g., *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (applying New York law); *Skill* v. *Martinez*, 91 F.R.D. 498, 507 (D. N.J. 1981), aff'd, 677 F.2d 368 (3d Cir. 1982); *Goodson* v. *Searle Laboratories*, 471 F. Supp. 546, 549 (D. Conn. 1978); *Dunkin* v. *Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977); *Chambers* v. *G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975), aff'd per curiam, 567 F.2d 269 (4th Cir. 1977); *Carmichael* v. *Reitz*, 17 Cal. App. 3d 958, 989 (1971); *Hamilton* v. *Hardy*, 37 Colo. App. 375, 387 (1976); *Mahr* v. *G.D. Searle & Co.*, 72 Ill. App. 3d 540, 561

Frumer and Friedman, Products Liability §§ 8.01, 8.03 [3] (1983 & Supp. 1984); Restatement (Second) of Torts, *supra* at § 452, comment f.

The rule in jurisdictions that have addressed the question of the extent of a manufacturer's duty to warn in cases involving prescription drugs is that the prescribing physician acts as a "learned intermediary" between the manufacturer and the patient, and "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty." *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 386-387 (1974). Oral contraceptives, however, bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks. Whereas a patient's involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use "the pill," as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.[10]

Furthermore, the physician prescribing "the pill," as a matter of course, examines the patient once before prescribing an oral contraceptive and only annually thereafter. J. Willson, E. Carrington, & W. Ledger, Obstetrics and Gynecology 184 (7th

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(1979); *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 43 (1979); *Seley* v. *G.D. Searle & Co.* , 67 Ohio St. 2d 192, 198 (1981); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 385 (1974); *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 431 (1973). See also *Terhune* v. *A.H. Robins Co.*, 90 Wash. 2d 9, 14 (1978) (intrauterine contraceptive device).

10 According to the American Medical Association, "the medical profession regards the pill, in most cases, as a convenience rather than a traditional medication." Statement of American Medical Association, published in Science News, March 14, 1970, quoted in Comment, Liability of Birth Control Pill Manufacturers, 23 Hastings L.J. 1526, 1532 (1972). These distinguishing features have been recognized by legal commentators as well as by the medical profession. See Merrill, Compensation for Prescription Drug Injuries, 59 Va. L. Rev. 1, 91, 93 (1973); Comment, Liability of Birth Control Pill Manufacturers, 23 Hastings L.J. 1526, 1538-1543 (1972).

ed. 1983). D. Danforth, Obstetrics and Gynecology 267 (4th ed. 1982). T. Green, Gynecology: Essentials of Clinical Practice 593 (3d ed. 1977). At her annual checkup, the patient receives a renewal prescription for a full year's supply of the pill.[11] Thus, the patient may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician. Even if the physician, on those occasions, were scrupulously to remind the patient of the risks attendant on continuation of the oral contraceptive, "the patient cannot be expected to remember all of the details for a protracted period of time." 35 Fed. Reg. 9002 (1970).

Lastly, the birth control pill is specifically subject to extensive Federal regulation. The FDA has promulgated regulations designed to ensure that the choice of "the pill" as a contraceptive method is informed by comprehensible warnings of potential side effects.[12] See notes 3 and 4 *supra*. These regulations, and subsequent amendments, have their basis in the FDA commissioner's finding, after hearings, that "[b]ecause oral contraceptives are ordinarily taken electively by healthy women who have available to them alternative methods of treatment, and because of the relatively high incidence of serious illnesses associated with their use, . . . users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks." 43 Fed. Reg. 4215 (1978). The FDA also found that the facts necessary to informed decisions by women as to use of oral contraceptives are "too complex to expect the patient to remember everything told her by the physician," and that, in the absence of direct

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11 MacDonald saw her gynecologist once in the summer of 1973, once in the summer of 1974, and once in August of 1975. At each appointment, she received a prescription for birth control pills. Thus, eleven months had elapsed between her last gynecological checkup and her stroke in July, 1976.

12 See 21 C.F.R. § 130.45(a), 35 Fed. Reg. 9002 (1970) (oral contraceptives "are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception"); 43 Fed. Reg. 4215 (1978).

written warnings, many potential users of "the pill" do not receive the needed information "in an organized, comprehensive, understandable, and handy-for-future-reference form." 35 Fed. Reg. 9002 (1970).

The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered. We conclude that the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user. Thus, the manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer.[13]

2. *Adequacy of the warning.* Because we reject the judge's conclusion that Ortho had no duty to warn MacDonald, we turn to Ortho's separate argument, not reached by the judge, that the evidence was insufficient to warrant the jury's finding that Ortho's warnings to MacDonald were inadequate. Ortho contends initially that its warnings complied with FDA labeling requirements, and that those requirements preempt or define

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13 This opinion does not diminish the prescribing physician's duty to "disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to" take "the pill." *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152, 155 (1982).

the bounds of the common law duty to warn. We disagree. The regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect. In response to concerns raised by drug manufacturers that warnings required and drafted by the FDA might be deemed inadequate by juries, the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law. 43 Fed. Reg. 4214 (1978). Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise oral contraceptive users of inherent risks, the manufacturer should not be shielded from liability by such compliance. See *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Skill* v. *Martinez*, 91 F.R.D. 498, 508 (D.N.J. 1981); *Stevens* v. *Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 397-398 (1974). Cf. *Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 (1st Cir. 1965); *Ferebee* v. *Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982). See generally 1A Frumer & Friedman, Products Liability § 8.07[1] (1983). Thus, compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence. See *Deignan* v. *Lubarsky*, 318 Mass. 661, 664 (1945). See also *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 965 (E.D. Wis. 1981). We therefore concur with the plaintiffs' argument that even if the conclusion that Ortho complied with FDA requirements were inescapable, an issue we need not decide, the jury nonetheless could have found that the lack of a reference to "stroke" breached Ortho's common law duty to warn.

The common law duty to warn, like the analogous FDA "lay language" requirement, necessitates a warning "comprehensible to the average user and . . . convey[ing] a fair indication

of the nature and extent of the danger to the mind of a reasonably prudent person." *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 49 (1979), quoting *Spruill* v. *Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir. 1962). Whether a particular warning measures up to this standard is almost always an issue to be resolved by a jury; few questions are "more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person." *Ferebee* v. *Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982). See *Hayes* v. *Ariens Co.*, 391 Mass. 407, 409-410 (1984). A court may, as a matter of law, determine "whether the defendant has conformed to that standard, in any case in which the jury may not reasonably come to a different conclusion," Restatement (Second) of Torts § 328B (d) and comment g (1965), but judicial intrusion into jury decision-making in negligence cases is exceedingly rare. See *Croley* v. *Matson Navigation Co.*, 434 F.2d 73, 75 (5th Cir. 1970). Further, we must view the evidence in the light most favorable to the plaintiffs. *Uloth* v. *City Tank Corp.*, 376 Mass. 874, 876 (1978). The test is whether "anywhere in the evidence, from whatever source derived, any combination of circumstances could be found from which a reasonable inference could be drawn in favor of the plaintiff." *Poirier* v. *Plymouth*, 374 Mass. 206, 212 (1978), quoting *Raunela* v. *Hertz Corp.*, 361 Mass. 341, 343 (1972). Accord *Michnik-Zilberman* v. *Gordon's Liquor, Inc.*, 390 Mass. 6, 7n.1 (1983).

Ortho argues that reasonable minds could not differ as to whether MacDonald was adequately informed of the risk of the injury she sustained by Ortho's warning that the oral contraceptives could cause "abnormal blood clotting which can be fatal" and further warning of the incremental likelihood of hospitalization or death due to blood clotting in "vital organs, such as the brain." We disagree. "The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. . . . The adequacy of such warnings is measured not only by what is stated, but also by the manner in

which it is stated. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency." *Seley* v. *G.D. Searle Co.*, 67 Ohio St. 2d 192, 198 (1981). We cannot say that this jury's decision that the warning was inadequate is so unreasonable as to require the opposite conclusion as a matter of law.[14] The jury may well have concluded, in light of their common experience and MacDonald's testimony, that the absence of a reference to "stroke" in the warning unduly minimized the warning's impact or failed to make the nature of the risk reasonably comprehensible to the average consumer. Similarly, the jury may have concluded that there are fates worse than death, such as the permanent disablement suffered by MacDonald, and that the mention of the risk of death did not, therefore, suffice to apprise an average consumer of the material risks of oral contraceptive use. Cf. *Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 (1st Cir. 1965).

Ortho's argument that, as a matter of law, there was insufficient evidence that MacDonald's injury was proximately caused by a deficiency in the warnings is substantially similar to its argument on the issue of the adequacy of the warnings, and is likewise unavailing. Relying on *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152 (1982), for the proposition that MacDonald had the burden of proving causation by showing that "had the proper information been provided neither [s]he nor a reasonable person in similar circumstances" would have accepted Ortho's pills as a contraceptive method, *id.* at 158, Ortho argues that "[t]here was no evidence that a reasonable person, having been informed of the risk of death by abnormal blood clotting and having chosen to assume the risk, would have acted differently if informed of the risk of 'stroke.' " The jury were free, however, to credit MacDonald's

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14 See Weinberger, Collateral Estoppel and the Mass Produced Product: A Proposal, 15 New Eng. L. Rev. 1, 36-38 (1980).

testimony that she would not have used the pills had she been advised of the danger of "stroke," and to infer that an explicit reference to the risk of stroke might tip the balance in a reasonable person's choice of a contraceptive method. Ortho also asserts that evidence that MacDonald did not ask her gynecologist for an explanation of the meaning of "abnormal blood clotting" or inform him of two episodes of numbness in her hand subsequent to her initiation of oral contraceptive use indicates that MacDonald was not disposed to heed Ortho's warnings, and, consequently, that the evidence did not permit an inference that a different warning by Ortho would have affected MacDonald's decision to use Ortho's pills. These arguments raise the issue of the plaintiff Carole MacDonald's comparative negligence. That issue was not raised below and thus is not before us. *Kagan* v. *Levenson*, 334 Mass. 100, 106 (1956).

We reverse the judgment, which the judge ordered notwithstanding the verdict, and remand the case to the Superior Court for the entry of judgment for the plaintiffs.

*So ordered.*

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O'CONNOR, J. (dissenting). The court reverses the judgment below and holds Ortho Pharmaceutical Corporation (Ortho) liable to Carole and Bruce MacDonald even though the jury found that Ortho adequately informed Carole MacDonald's physician of the risks associated with the use of its contraceptive pills, and regardless of whether Ortho complied with the applicable Federal Food and Drug Adminstration (FDA) regulations governing the provision of printed information to users of oral contraceptives. I would hold that, as a matter of law, by adequately informing physicians of the risks associated with its product and by complying with applicable FDA regulations, a contraceptive pill manufacturer fulfils the duty to warn that it owes consumers. Therefore, because the jury found that Ortho adequately warned Carole MacDonald's physician of the risks associated with its contraceptive pills and because the MacDonalds presented no evidence that Ortho

failed to comply with FDA regulations, I would affirm the judgment for Ortho.

In order to fulfil its duty to warn consumers of risks associated with its product, a manufacturer of a nonprescription ("over-the-counter") drug must place on the drug's package printed warnings. That duty "derives from the basic marketing predicate of the over-the-counter drug industry, namely, that nonprescription drugs are purchased by consumers for the purpose of self-medication *typically without any intended or actual intervention by a physician*." *Torsiello* v. *Whitehall Laboratories*, 165 N.J. Super. 311, 322 (1979) (emphasis added). In contradistinction, a manufacturer of a prescription drug fulfils its duty to warn a consumer by adequately informing the consumer's physician—a "learned intermediary between the purchase and the manufacturer"—of the drug's associated risks. *Sterling Drug, Inc.* v. *Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). That rule results from the fact that, by definition, before a consumer uses a prescription drug, that consumer must have some interaction with a doctor. See 21 U.S.C. § 353(b)(1) (1982).[1] In cases involving manufacturers of contraceptive pills, every court but one has adhered to the "prescription drug" rule. See *Hamilton* v. *Hardy*, 37 Colo. App. 375, 387 (1976); *Mahr* v. *G.D. Searle & Co.*, 72 Ill. App.

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1 Section 353(b)(1) provides: "A drug intended for use by man which—(A) is a habit-forming drug to which section 352(d) of this title applies; or (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application uder section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

3d 540, 561 (1979); *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 43 (1979); *Cobb* v. *Syntex Laboratories, Inc.*, 444 So.2d 203, 205 (La. App. 1983); *Seley* v. *G.D. Searle & Co.*, 67 Ohio St. 2d 192, 202-203 (1981); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 385 (1974); *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 431 (1973); *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981); *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Goodson* v. *Searle Laboratories*, 471 F. Supp. 546, 548 (D. Conn. 1978); *Dunkin* v. *Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (D. Tenn. 1977); *Chambers* v. *G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975); *Skill* v. *Martinez*, 91 F.R.D. 498, 507 (D.N.J. 1981). See also *Carmichael* v. *Reitz*, 17 Cal. App. 3d 958, 989 (1971) (oral contraceptive pills used to treat woman for endometriosis and to aid her to become pregnant); *Terhune* v. *A.H. Robins Co.*, 90 Wash. 9, 13 (1978) (intrauterine contraceptive device). But see *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963, amended by order, 532 F.Supp. 211 (D. Wis. 1981). The one court that went beyond the prescription drug rule, see *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, *supra*, imposed on Ortho the duty to adequately inform physicians of the contraceptive pill's risks and to comply with applicable FDA regulations. 532 F. Supp. at 213. To my knowledge, no other court has embraced the rule laid down today by the court.

Before prescribing any drug, whether on the doctor's initiative or at the patient's request, the doctor must exercise professional judgment as to the medical propriety of that patient's taking that drug and, in exercising that judgment, the doctor must conform to the standards of good medical practice laid down in *Brune* v. *Belinkoff*, 354 Mass. 102, 109 (1968). Furthermore, this court has held that a doctor must "disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152, 155 (1982). That rule applies

when a physician prescribes a drug just as it does when a physician performs any other medical procedure. "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to [use the drug]." *Id.* at 156, quoting from *Wilkinson* v. *Vesey*, 110 R.I. 606, 627 (1972). "Appropriate information may include . . . the nature and probability of risks involved, the benefits to be reasonably expected, the inability of the physician to predict results, . . . , and the available alternatives, including their risks and benefits." *Id.*

Unless doctors have current, accurate, and complete information about a drug's risks, they cannot properly perform their vital role. Therefore, courts have imposed on drug manufacturers the duty to provide doctors with that information. See, e.g., *Brochu* v. *Ortho Pharmaceutical Corp.*, *supra* at 657-659. A drug manufacturer who fails properly to fulfil that duty must respond in damages to a patient who suffers an injury as a result. See, e.g., *McEwen* v. *Ortho Pharmaceutical Corp.*, *supra* at 386-387.

I believe that the "prescription drug" rule, combined with the *Harnish* rule, most fairly and efficiently allocates among drug manufacturers, physicians, and drug users, the risks and responsibilities involved with the use of prescription drugs. Furthermore, I believe that those rules best ensure that a prescription drug user will receive in the most effective manner the information that she needs to make an informed decision as to whether to use the drug. The rules place on drug manufacturers the duty to gather, compile, and provide to doctors data regarding the use of their drugs, tasks for which the manufacturers are best suited, and the rules place on doctors the burden of conveying those data to their patients in a useful and understandable manner, a task for which doctors are best suited. Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in

position to give adequate advice directly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk. Prescription drugs—including oral contraceptives—differ from other products because their dangers vary widely depending on characteristics of individual consumers. Exposing a prescription drug manufacturer to liability based on a jury's determination that, despite adequately informing physicians of the drug's risks and complying with FDA regulations, the manufacturer failed reasonably to warn a particular plaintiff-consumer of individualized risks is not essential to reasonable consumer protection and places an unfair burden on prescription drug manufacturers.

Even though the court recognizes the universal application of the "prescription drug" rule, it states that "[o]ral contraceptives . . . bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks." *Ante* at ____ . The court attempts to distinguish contraceptive pills from other prescription drugs by comparing the relative involvement of doctor and patient in the prescribing process. "Whereas a patient's involvement in decision-making concerning use of prescription drug necessary to treat a malady is typically minimal or nonexistent," the court asserts, "the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use 'the pill,' as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role." *Ante* at ____-____. In making that statement, the court not only assumes facts not established on the record but also disregards the mandate of *Harnish* v. *Children's Hosp. Medical Center, supra.*

While I would choose the "prescription drug" rule over the rule announced today by the court, I recognize that the FDA has promulgated regulations governing the provision of printed information to users of oral contraceptives. I would not consider the imposition of tort liability for failure to comply with those regulations, designed to further consumer protec-

tion, unfair nor unduly burdensome to contraceptive pill manufacturers. However, in my view, the evidence in this case would not support a finding that Ortho failed to comply with those regulations. The FDA required Ortho to place on every oral contraceptive pill dispenser a warning stating that the "most serious known side effect [of the oral contraceptive pill] is abnormal blood clotting which can be fatal." 21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970). Ortho complied in every way with that requirement. The FDA also required that Ortho make available to physicians for patients who requested it "information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions." 21 C.F.R. § 130.45(e), 35 Fed. Reg. 9003 (1970). Ortho provided Carole MacDonald's physician with a booklet that stated: "Blood clots occasionally form in the blood vessels of the legs and pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain." MacDonald's physician gave Ortho's booklet to MacDonald. The court finds it unnecessary to decide whether Ortho complied with FDA's "lay language" requirement, *ante* at ____, but I do not believe that any rational trier of fact could have concluded that Ortho failed to comply with the regulation.

Furthermore, even if there be a common law duty necessitating a direct warning to the consumer with respect to the "nature and extent of the danger" of contraceptive pills, as the court declares, the MacDonalds presented no evidence that Ortho failed to fulfil that duty. The court states only that the jury "could have found that the lack of a reference to 'stroke' breached Ortho's common law duty to warn." *Ante* at ____. Surely, the statement in Ortho's booklet that the contraceptive pill could cause life threatening blood clots to form in the brain, even though it did not contain the word 'stroke,' satisfied the court's requirement that Ortho provide "written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects." *Ante* at ____-____. I would affirm the judgment for Ortho.

**Decision of the Superior Court**

COMMONWEALTH OF MASSACHUSETTS
WORCESTER, SS.

Superior Court Civil Action No. 10422

CAROL D. MACDONALD and another[1]

vs.

ORTHO PHARMACEUTICAL CORPORATION

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

This matter is before the court on the defendant's motion for judgment notwithstanding the verdict. See Mass. R. Civ. P. 50(b). The defendant claims that it is entitled to judgment in its favor as a matter of law because the plaintiff failed to adduce evidence of negligence or breach of warranty by the defendant. At the close of evidence, the defendant filed a motion for directed verdict on the same grounds, thus satisfying the procedural requirements of Mass. R. Civ. P. 50(b).

This is a products liability action in which the plaintiff claims that she suffered a stroke as a result of ingesting the defendant's product, Ortho Novum, an oral contraceptive. In answering special questions, the jury found that the defendant did not breach any warranties and was not negligent in its manufacture of the drug nor in its warnings to the prescribing physician. The jury did find, however, that the defendant was negligent and breached its warranty of merchantability by failing to adequately warn the plaintiff of possible side effects. As a result, the jury awarded $800,000 in damages to the plaintiff and $50,000 to her husband.

1 Bruce MacDonald.

The defendant brought this motion for judgment notwithstanding the verdict within ten days after the jury returned its verdict. See Mass. R. Civ. P. 50(b) (party may move for judgment n.o.v. not later than ten days after entry of judgment). In support of its motion, the defendant argues that because the product was a prescription drug, the defendant's only duty was to warn the physician of potential side effects, not the plaintiff. Consequently, the defendant argues that the jury's finding that the warning to the physician was adequate requires a judgment in its favor as a matter of law.

Massachusetts has not adopted the strict liability theory expressed in the Restatement (Second) of Torts, § 402A (1965). See *Swartz* v. *General Motors Corp.*, 375 Mass. 628, 630 (1978). Instead, products liability based on negligence and breach of warranty is the functional equivalent of strict liability. *Back* v. *Wickes*, 375 Mass. 633, 639 (1978). In Massachusetts, therefore, a claim for breach of warranty is "congruent in nearly all respects with the principles expressed in . . . § 402A." *Id.* at 640. Consequently, because there are no reported Massachusetts appellate court opinions on prescription drug manufacturers' duty to warn, c.f. *Payton* v. *Abbott Labs*, 512 F.Supp. 1031 (1981), this court may follow the principles of § 402A in this case.

Comment k to § 402A defines drugs as "unavoidably unsafe products" and provides as follows:

> "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. * * * Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians. * * * The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to

> be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

A majority of courts in this country have held that a manufacturer has satisfied its duty to warn upon adequately informing the prescribing physician of potential side effects. See, e.g. *Goodson* v. *Searle Laboratories*, 471 F.Supp. 546, 548 (Conn. 1978); *Dunkin* v. *Syntex Laboratories, Inc.*, 443 F.Supp. 121, 123 (Tenn. 1977). Except where the Food and Drug Administration (FDA) regulations otherwise provide, courts have held that there is no duty to warn the patient because the prescribing physician acts as an informed intermediary between the manufacturer and the patient. See *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F.Supp. 961, 963 (E.D. Wis. 1981). I am of the opinion that the general rule expressed by § 402A is applicable to this case, and therefore conclude that the defendant fulfilled its duty to warn upon adequately informing the plaintiff's physician of potential side effects.

FDA regulations also require that certain warnings be made to patients in the form of package inserts and labels. 21 C.F.R. § 310.501. Although the plaintiff does not contest that defendant complied with the FDA labeling and packaging requirements, she asserts that the defendant had an additional duty to warn her of side effects beyond the duty required by FDA regulations. She asserts that the defendant, having undertaken albeit involuntarily to communicate a direct warning to her through a label on the package had a duty to provide an adequate warning and failed in that regard. This argument has appeal, since the average consumer would be unaware of the FDA regulations and might feel she could rely on the mandated warning as all embracing. However, I have found no case law or authoritative text addressing itself to this issue either

pro or con. It would constitute an exception to the Restatement position supra p. 3 and I do not consider it appropriate therefore for me at this trial stage level to support the verdict on this principle. Accordingly, the question as to whether the warnings printed on the package were adequate as a matter of law need not be decided by me.

Consequently, because the jury found that the defendant adequately warned the plaintiff's physician, the defendant is entitled to judgment in its favor as a matter of law.

ORDER

It is therefore *Ordered* that defendant's motion for judgment notwithstanding the verdict be *Allowed*.

/s/ WILLIAM C. O'NEIL, JR.
William C. O'Neil, Jr.
*Justice of the Superior Court*

ENTERED: July 29, 1983.

**Judgment of the Supreme Judicial Court**

COMMONWEALTH OF MASSACHUSETTS
SUPREME JUDICIAL COURT FOR THE COMMONWEALTH

At Boston, February 28, 1985

In the Case No. SJC-3489

CAROLE D. MACDONALD & another

vs.

ORTHO PHARMACEUTICAL CORPORATION

pending in the Superior Court Department of the Trial Court for the County of Worcester No. 10422.

ORDERED, that the following entry be made in the docket; viz.,—

We reverse the judgment, which the judge ordered notwithstanding the verdict, and remand the case to the Superior Court for the entry of judgment for the plaintiffs.

By the Court,

/s/ JEAN M. KENNETT
*Clerk*

February 28, 1985

See opinion on file.

**Denial of the Petition for Rehearing**

SUPREME JUDICIAL COURT
FOR THE COMMONWEALTH

Room 1412 Court House
Boston, Massachusetts 02108
(617) 725-8055

JEAN M. KENNETT
*Clerk*

FREDERICK J. QUINLAN
*Assistant Clerk*

April 1, 1985

Edward P. Leibensperger, Esq.
Martin C. Pentz, Esq.
Nutter, McClennen & Fish
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210

Gentlemen: Re: Carole D. MacDonald & another
vs. Ortho Pharmaceutical Corporation
Supreme Judicial Court No. SJC-3489

Your Petition for Rehearing in the above captioned appeal has been considered by the court and is denied.

Very truly yours,

/s/ DOLORES G. DUPRÉ
Dolores G. Dupré
for Jean M. Kennett, *Clerk*

c.c.: John F. Keenan, Esq.
Wolfson, Dodson, Keenan & Cotton
390 Main St., Worcester 01608

Robert D. Horton, Esq.
Edward P. Healy, Esq.
390 Main St., Worcester 01608

David F. Dobbins, Esq.
Patterson, Belknap, Webb & Tyler
30 Rockefeller Plaza, New York, NY 10112

Robert W. Sparks, Esq.
John N. Beidler, Esq.
1 Johnson & Johnson Plaza, New Brunswick, NJ 08933

**Judgment of the Superior Court**

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF THE TRIAL COURT
WORCESTER, SS.

Superior Court Civil Action No. 10422

CAROLE D. MACDONALD and BRUCE M. MACDONALD,
*Plaintiffs,*

—VS.—

ORTHO PHARMACEUTICAL CORPORATION,
*Defendant.*

JUDGMENT NOTWITHSTANDING THE VERDICT

This action came on to be heard on the defendant Ortho Pharmaceutical Corporation's motion for Judgment Notwithstanding the Verdict, and after hearing,

It is ORDERED and ADJUDGED

That the plaintiffs take nothing, that the action be dismissed, and that the defendant recover of the plaintiffs its costs of action.

By the Court, (W.C. O'Neil, J.)

/s/ [Illegible]
*Assistant Clerk*

Dated: August 1, 1983

copies mailed 8-1-83z
J.F. Keenan
C. Barrett
E. Leibensperger
R.W. Sparks
E.P. Healy

**Special Interrogatory Responses from the Jury**

COMMONWEALTH OF MASSACHUSETTS
WORCESTER, SS.

Superior Court Civil Action No. 10422

CAROLE D. MACDONALD and BRUCE MACDONALD,
*Plaintiffs,*

—vs.—

ORTHO PHARMACEUTICAL CORPORATION,
*Defendant.*

SPECIAL JURY VERDICT

1. Was the plaintiff's stroke caused by an oral contraceptive manufactured by the defendant?

Yes X No ____

If your answer to Question No. 1 is "No", then cease your deliberations and return your verdict. If your answer is "Yes", continue.

2. Was the defendant negligent as to:

(a) in the manufacture of the pill? Yes ____ No X

(b) in its warnings to Dr. Powell? Yes ____ No X

(c) in its warnings to the plaintiff? Yes X No ____

3. If so was such negligence a proximate cause of the plaintiff's injuries as to:

(a) the manufacture of the pill? Yes ____ No X

(b) in its warnings to Dr. Powell? Yes ____ No X

(c) in its warnings to the plaintiff? Yes X No ____

4. Did the defendant breach a warranty of merchantability as to:

   (a) in the manufacture of the pill? Yes ____ No X

   (b) in its warnings to Dr. Powell? Yes ____ No X

   (c) in its warnings to the plaintiff? Yes X No ____

5. If so was such breach of warranty a proximate cause of the plaintiff's injuries as to:

   (a) the manufacture of the pill? Yes ____ No X

   (b) in its warnings to Dr. Powell? Yes ____ No X

   (c) in its warnings to the plaintiff? Yes X No ____

   (If your answer to Question No. 3 and 5 and each of their respective sub-parts is "No", then cease your deliberations and return your verdict.)

6. Apart from the question of negligence or breach of warranty state the amount in dollars and cents, that you determine would adequately compensate the plaintiff Carole D. MacDonald for her injuries? (Write out in words and in figures.)

   eight hundred thousand dollars and

   no cents. ($800,000.00)

7. Apart from the question of negligence or breach of warranty state the amount in dollars and cents that you determine would adequately compensate the plaintiff Bruce MacDonald for his claimed loss of consortium? (Write out in words and in figures.)

   fifty thousand dollars and

   no cents. ($50,000.00)

/s/ ANNA M. HOWARD
*Forelady of the Jury*

DATED: April 26, 1983.

## Constitutional Provisions Involved

*Amend. XIV, § 1 (Due Process Clause)*

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

**Letter from Walter C. Bornemeier, M.D., President of the American Medical Association, to the Medical Community**

AMERICAN MEDICAL ASSOCIATION
535 North Dearborn Street, Chicago, Illinois 60610
Phone (312) 527-1500 TWX 910-221-0300

August 17, 1970

Dear Doctor:

As required by Federal regulation, all containers of the oral contraceptives will henceforth contain a package insert, written for the patient, which calls attention to certain hazards of "the pill." The insert also mentions the availability of an informative pamphlet on the pill which the patient can obtain from her physician.

As a service to the medical profession, and in cooperation with the American College of Obstetricians and Gynecologists and the Food and Drug Administration, the American Medical Association has prepared the enclosed authoritative and informative brochure on the oral contraceptive. We feel that this publication, written in easily understood language, puts the hazards of the pill in proper perspective.

This AMA effort is designed to reinforce the role of the physician as the best source of patient information. We enlist your cooperation in making this booklet available to all of your patients who are on the pill.

Additional copies of the brochure for you to give your patients can be obtained at no charge from the AMA Order Department. Non M.D.'s can purchase copies from the AMA Order Department.

More information on this unique AMA service was published in the August 10th issue of the *American Medical News*.

Sincerely,

/s/ WALTER C. BORNEMEIER, M.D.
Walter C. Bornemeier, M.D.

enclosure

Supreme Court, U.S.
FILED
SEP 27 1985
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-354

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1985

ORTHO PHARMACEUTICAL CORPORATION,
*Petitioner,*

v.

CAROLE MACDONALD AND BRUCE MACDONALD,
*Respondents.*

## BRIEF OF RESPONDENTS IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT OF MASSACHUSETTS

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## QUESTIONS PRESENTED

1. Has the Petitioner timely and properly raised a Federal question so as to give this Court jurisdiction to review the judgment of the Supreme Judicial Court of Massachusetts on a Writ of Certiorari?

2. Does the Petition present any substantial Federal question arising out of the proceedings below which is appropriate for review on Writ of Certiorari?

## LIST OF PARTIES TO THE APPEAL IN THE SUPREME JUDICIAL COURT OF THE COMMONWEALTH OF MASSACHUSETTS

The names of all of the parties to the appeal in the Supreme Judicial Court of Massachusetts are contained in the caption to this Petition and are set forth in page ii of the Petition for Certiorari.

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CAROLE MACDONALD AND BRUCE MACDONALD,
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## BRIEF OF RESPONDENTS IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT OF MASSACHUSETTS

---

Respondents, Carole MacDonald ("Mrs. MacDonald") and her husband, Bruce MacDonald ("Bruce"), respectfully request that this Court dismiss or, in the alternative, deny the Petition for a Writ of Certiorari of Ortho Pharmaceutical Corporation ("Ortho").

### OPINIONS AND JUDGMENTS BELOW

The opinion of the Supreme Judicial Court of Massachusetts and a reiteration of the judgment and proceedings below have been reprinted by Ortho in the Appendix to its Petition, at Pages 1 a through 27 a.

## OBJECTIONS TO JURISDICTION

Pursuant to Rule 22.3, the Respondents object to the jurisdiction of this Court to grant the Writ of Certiorari.

Ortho attempts to invoke jurisdiction under 28 U.S.C. § 1257(3), based upon a claim that the lower court judgment deprived it of constitutional rights under the Due Process Clause of the Fourteenth Amendment (Pet. p. 2).

If review of the judgment of a State Court is sought, Rule 21.1(h) of this Court requires that the Petition for Certiorari, in its statement of the case, "specify the stage in the proceedings, both in the court of first instance and in the appellate court, at which the federal questions sought to be reviewed were raised; the method or manner of raising them and the way in which they were passed upon by the court;".

In the litigation here, no Federal question was raised in the Trial Court (Massachusetts Superior Court) or prior to the decision of the Appellate Court (Supreme Judicial Court of Massachusetts).

As conceded in its Petition (p. 6), Ortho first purported to raise its constitutional issue in a Petition for Rehearing to the Appellate Court, which was considered and denied by the Court, without comment (Pet. p. 23a).

This Court has always held that it is a prerequisite to the consideration here of a Federal question coming from a State Court that the question should have been raised in that Court before decision, or that it should have been actually entertained and considered upon a Petition for Rehearing. A mere denial of such a petition by the State Court, without opinion, is not enough. *Tidal Oil Co.* v. *Flanagan*, 263 U.S. 444, 455 (1924); *Rooker* v. *Fidelity Trust Co.*, 261 U.S. 114, 117 (1923).

It is apparent from the record in the proceedings below, that the distinction between oral contraceptives and other

prescription drugs and the scope of regulations of the United States Food and Drug Administration ("FDA") over labelling of such products were put in issue by the briefs and arguments in the lower Appellate Court and Ortho cannot now claim that the ruling of the Court on these issues could not have been anticipated by it in the original hearing.

The record does not establish, affirmatively or by fair implication, whether a resolution of the claimed Federal question was necessary to the Court's determination, or whether its decision was based on adequate and independent state grounds. *Boughton* v. *Exchange Bank*, 104 U.S. 427 (1881).

A party who seeks and is given an opportunity in a State Court to litigate rights claimed by it cannot have the judgment reviewed here on the ground that due process of law was denied, because the litigation did not result successfully. *Remington Paper Co.* v. *Watson*, 173 U.S. 443, 451 (1899).

For the foregoing reasons, it appears that Ortho has failed to establish grounds on which the jurisdiction of this Court may be invoked on Certiorari, and therefore, this Petition ought to be dismissed.

## CONSTITUTIONAL PROVISION INVOLVED

The only constitutional provision relied upon by Ortho is U. S. Const. Amend. XIV §1 (Due Process Clause), which is reprinted in the Appendix to its Petition, at page 28 a.

## STATEMENT OF THE CASE

This is a products liability action for personal injuries sustained by Mrs. MacDonald and for consequential damages and loss of consortium sustained by her husband,

Bruce, resulting from Mrs. MacDonald's use of birth control pills manufactured by Ortho (R. 10-13).

During the early morning hours of July 24, 1976, Mrs. MacDonald suffered a cerebral vascular accident, otherwise known as a stroke (R. 153). Mrs. MacDonald's stroke was caused by her use of Ortho-Novum, a birth control pill manufactured by Ortho (R. 153-154, 187, 361, 364, 365-366, 392, 393). The stroke caused brain death to about 20 percent of her brain (R. 352). A seizure disorder in turn resulted from the cerebral scar caused by the stroke (R. 159). Mrs. MacDonald was 29 years old at the time of her stroke (R. 156). She is totally and permanently disabled from useful and substantial employment (R. 372).

After a trial in the Superior Court of the Commonwealth of Massachusetts, Worcester County Division, the jury returned a special verdict, finding that Mrs. MacDonald's stroke was caused by an oral contraceptive manufactured by Ortho, that Ortho was negligent and breached its warranty of merchantability in its warnings to Mrs. MacDonald, that Mrs. MacDonald's damages were in the amount of $800,000.00, and that her husband Bruce's damages were in the amount of $50,000.00 for consequential damages and loss of consortium (R. 40-41). The Supreme Judicial Court of Massachusetts affirmed the jury verdict.

Mrs. MacDonald visited a physician in 1973 because she was getting married and wanted to take birth control pills; the physician gave her a prescription (R. 144, 165). At that time, she was given a booklet about the pill (R. 167). The booklet was dated October of 1972 and was entitled "After your doctor prescribes Ortho-Novum" (R. 58, 168). Ortho distributed this booklet for doctors to give to their patients in 1973 (R. 290, 169). These were called "patient information booklets" (R. 92). Carole read the booklet, but it did not say anything about stroke (R. 164). She received no other literature of any type from Ortho concerning the pill (R. 165).

The FDA regulations mandated that a warning by the manufacturer of oral contraceptives be included with the pill packet dispensed to a patient, and that the manufacturer make other written, printed, or graphic materials available to patients (R. 79-81). The regulations also mandated "that information in lay language concerning effectiveness, contra-indications, warnings, precautions, and adverse reactions be incorporated prominently in the beginning of any such materials" (R. 81). Ortho's 1973 patient information booklet did not mention the risk of "stroke" (R. 58-73). However, Ortho changed the booklet in 1978 to include the following warning: "Blood clots (in various blood vessels of the body) are the most common of the serious side effects of oral contraceptives. A clot can result in a stroke (if the clot is in the brain), a heart attack (if the clot is in a blood vessel of the heart) . . .".[1]

Mrs. MacDonald used Ortho-Novum 1/80 birth control pills from 1973 to 1976 (R. 161, 162). During that time, she did not know what "abnormal blood clotting" meant, but did know what "stroke" meant; had she been warned that the pill caused strokes, she would not have used the pill (R. 164).

Ortho's recommended "dosage and administration" of the oral contraceptive prescribed to Mrs. MacDonald was one tablet daily from the 5th through the 25th day of the menstrual cycle, and supplied the pills in various containers, including bottles of 500 tablets (R. 56). Mrs. MacDonald visited the prescribing physician annually, each time receiving a checkup and a prescription for one year's supply of birth control pills (R. 144, 145).

The risk of stroke was 4.1 to 9.5 times greater in oral contraceptive users than in non-users (R. 84). One study

---

[1] See Lindsay v. Ortho Pharmaceutical Corp., 481 F. Supp. 314, 350 (E.D.N.Y. 1979), 637 F. 2d 87 (2nd Cir. 1980).

showed the risk to be 15 or 20 times greater (R. 139). There were many other serious adverse reactions associated with the use of the pill (R. 85, 311, 313). Ortho was aware of these adverse reactions and the various studies that documented them (R. 83, 84).

Adverse reactions included thrombophlebitis, pulmonary embolism, cerebral thrombosis and hemorrhage, myocardial infarction, gallbladder disease, retinal thrombosis, optic neuritis, hepatic lesions with or without intra-abdominal bleeding, nausea, vomiting, gastrointestinal symptoms, breakthrough bleeding, spotting, change in menstrual flow, amenorrhea, edema, chioasma, melasma, cholastatic jaundice, migraine, rash (allergic), mental depression, change in weight, rise in blood pressure (R. 56, 85).

## REASONS FOR DENYING THE WRIT

Assuming, arguendo, that a Federal question was timely and properly raised in the lower court, Ortho's petition does not present any special and important reasons for this Court to exercise its discretion to review on a Writ of Certiorari.

This Court has before it a reasoned and principled decision of the highest court of the Commonwealth of Massachusetts. The decision is firmly grounded on state common law, is supported by the record in all respects, and does not involve any denial of due process. Ortho has not come forward with any reason to justify this Court becoming involved in this litigation.

### 1. Petitioner Has Failed To Meet This Court's Stringent Standards For Review Of The Decision Of The Highest Court Of A State.

Rule 17.1 requires that there be "special and important reasons" amplified in argument in a Petition for Certiorari

(Rule 21.1(j)), before this Court will exercise its discretion to grant review. The Court has repeatedly emphasized that it has limited reviewing powers and that it does not sit for the benefit of particular litigants. *Rice* v. *Sioux City Memorial Park Cemetery, Inc.*, 349 U.S. 70, 74 (1955).

Ortho admits that "the lower court's extension of its state law may not in and of itself raise a substantial federal question," but suggests that some important question of Federal law is raised by the "irregular manner" in which the Court adopted the new rule of law (Pet. p. 17).

Ortho does not advance any valid argument as to why this Court should abandon its time-honored and common sense reluctance to entangle itself in a state court decision involving state law issues. The standards for review of alleged constitutional violations differ dramatically when the matter for review is the decision of the highest court of a state, as opposed to a lower federal court. Great deference is accorded to the highest court of a state in its resolution of both factual and state law issues.

> "The choice for any state may be determined by the juristic philosophy of the judges of her courts, their conceptions of law, its origin and nature. We review not the wisdom of their philosophies, but the legality of their acts."

*Great Northern R. Co.* v. *Sunburst Oil & Ref. Co.*, 287 U. S. 358, 365 (1932).

Even in cases where there may have been an error of state law in the case below, this Court has strictly adhered to the view that such an error simply does not provide the basis for a legitimate claim of a denial of due process.

> "We are not at liberty to conjecture that the trial court acted under an interpretation of the state law different from that which we might adopt and then set up our own interpretation as a basis for declaring that due process has been denied. We cannot treat a

> mere error of state law, if one occurred, as a denial of due process; otherwise, every erroneous decision by a state court on state law would come here as a federal constitutional question."

*Gryger* v. *Burke*, 334 U. S. 728, 731, reh'g denied, 335 U. S. 837 (1948).

Moreover, the Constitution simply does not guarantee that the decisions of a state court be free from error or that such decisions shall be consistent. *Patterson* v. *Colorado ex rel Atty. Gen.*, 205 U. S. 454, 461 (1906); *Worcester County Trust Co.* v. *Riley*, 302 U. S. 292, 299 (1937).

**2. The Decision Of The Massachusetts Supreme Judicial Court Is Sound As A Matter Of State Common Law And Is Not Arbitrary And Unprincipled.**

Faced with the obstacle of presenting a substantial federal question under this Court's standards for review of the decision of the highest court of a state, Ortho appears to resort to an attack upon the Massachusetts Court and its decision in this case.

Thus, Ortho accuses the Court of *inventing ab initio* judicial findings of fact (Pet. p. 2); of relying upon non-judicial facts *conceived* during the appellate process (Pet. p. 3); engaging in *ex parte* fact finding (Pet. p. 3) proceeding to *make up* peculiar characteristics of oral contraceptives (Pet. p. 5); adopting *fictive* findings of fact (Pet. p. 6); turning the appellate process into a *de novo* and *ex parte* fact finding inquiry (Pet. p. 7); and of adopting *unprincipled* findings, which can only spur other courts to do likewise (Pet. p. 13). Sprinkling Latin phrases and catch-words throughout the Petition, however, does not fulfill the requirement of presenting special and important reasons for granting review on certiorari.

According to Ortho, the Massachusetts decision is "startling" (Pet. p. 3) and "trailblazes" new law (Pet.

p. 6). In fact, the Court simply decided an unsettled issue of state law, as to the extent of the duty to warn owed by a manufacturer of oral contraceptives to a consumer. The court determined that under Massachusetts law, there is a duty to warn the consumer directly of risks inherent in the use of the product and that Ortho breached its duty in failing to warn Mrs. MacDonald of the risk of the "stroke," which she suffered as a result of taking Ortho's birth control pills.

The decision below is well-reasoned and was not rendered in a cursory manner. The Appellate Court had the case under advisement from May 8, 1984 (when oral arguments were presented) until February 28, 1985 (when its opinion was issued). See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. 131 (1985).

In adopting its rule of law, the Massachusetts Court was free to reject the virtually unanimous rule elsewhere, that the prescription drug manufacturer must warn only the prescribing physician, not the patient. The Court engaged in a reasoned analysis of the rule and clearly scrutinized the reasons for it to determine whether its application was warranted in the case before it.

Although it recognized that the prescribing physician is a "learned intermediary" between the manufacturer and the patient, the Court established the necessity of a warning directly to the consumer in cases where, as here, oral contraceptives are prescribed. The rationale for the Court's decision is that oral contraceptives bear "peculiar characteristics" which set them apart from other prescription drugs. (See *MacDonald* v. *Ortho, supra,* 394 Mass. 136, 137).

The Court carefully delineated its reason for crafting an exception to the usual rule where oral contraceptives are involved. The distinctive nature of birth control pills was an issue raised in Mrs. MacDonald's appellate brief and in oral arguments presented to the Court, with ample data

to support the arguments. It is important to note that Mrs. MacDonald, like other healthy women, visited her physician, not because she was ill and desired that he prescribe a cure, but because she wanted to take the "pill" and needed a prescription in order to get it (R. 165).

In addition to considering analogous cases from other jurisdictions, the Massachusetts Court could and did consider scholarly treatises, the Restatement of the Law and germane law review articles. Faced with an unprecedented question of state law, a court may be guided by the law, which in its opinion, provides the most just and reasoned analysis. *Harrison* v. *McDonough Power Equipment, Inc.*, 381 F. Supp. 926, 930 (S.D. Fla. 1974).

The case does not, as Ortho contends, give rise to a "tremendous expansion of liability in prescription drug cases" (Pet. p. 3). The decision was limited to the failure to warn of "stroke" in cases involving oral contraceptives.

It is significant that Mrs. MacDonald suffered her stroke on July 24, 1976 (R. 153) and that, effective April 3, 1978, the FDA (by 43 Fed. Reg. 4221) amended its regulations to require that a birth control pill dispenser specify "stroke" as one of the potential serious side effects of the product.[2]

In compliance with the amended regulations, and for at least the past seven years, Ortho (and presumably, all other manufacturers of birth control pills) now provide a specific warning to the consumer of a risk of "stroke."[3]

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[2] See 21 C.F.R. § 310.501(a) 2 (iv) 1984.

[3] See *Lindsay* v. *Ortho Pharmaceutical Corp.*, 481 F. Supp. 314, 350 (E.D.N.Y. 1979).

### 3. The Massachusetts Decision Does Not Undermine FDA Regulations.

Dating back to at least 1970, the FDA recognized the necessity and feasibility of providing a direct warning to the consumer of the risks associated with birth control pills, and mandated the use of certain labelling in regard thereto.[4]

In 1976, when Mrs. MacDonald was stricken, oral contraceptives were the only prescription drug required to carry such a direct warning. (R. 286, 302, 305). Intrauterine devices and estrogen, progestational and isoproterenol products, which Ortho maintains are required by the FDA to carry a direct patient warning (Pet. p. 9 n. 2), did not become subject to such regulations until after 1976.

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[4] FDA regulations in effect during the time period relevant to this litigation required that the following warning be included in or with the dispenser:

> "DO NOT TAKE THIS DRUG WITHOUT YOUR DOCTOR'S CONTINUED SUPERVISION.
>
> "The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.
>
> "Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, (Firm name) has prepared a booklet (or other form) written in a style understandable to you as a drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.
>
> "Notify your doctor if you notice any unusual physical disturbance or discomfort."

21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970), recodified at 21 C.F.R. § 310.501(a)(4), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5354 (1974).

Although it determined that for the "safe and effective use" of oral contraceptives, a direct patient warning was required (21 C.F.R. § 310.501(a)(1)), the FDA, in adopting its regulations, did not intend to preempt or define the bounds of the common law duty to warn. This is clear from the preamble to its 1978 regulations.[5]

Thus, the Massachusetts Court was warranted in concluding (with ample citations of authority) that the FDA regulation mandated only a minimal warning requirement and that the jury could have reasonably concluded that the warning to Mrs. MacDonald was inadequate, because it did not advise her of the risks of "stroke." (See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. at 139, 140).

**4. Ortho's Claim Of Denial Of Due Process Is Unfounded.**

The gravamen of Ortho's Petition for Certiorari is that the Massachusetts Supreme Judicial Court denied it of due process because it allegedly engaged in "appellate fact-finding" and relied upon non-record evidence (Pet. p. 6).

Because we believe that the record is essential to a proper understanding of the case by this Court, counsel for the Respondents has requested the certification and transmission to this Court of the Appendix filed with the lower Appellate Court (Rule 19.1).

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[5] "The Commissioner does not agree that the imposition of a requirement for patient labeling will necessarily affect adversely the standard of civil tort liability which is imposed on drug manufacturers or dispensers. Whether or not a corporation or individual is to be held liable in a given situation will depend upon the facts surrounding the manufacture, sale, and use of the drug product, and on the nature of the injury. It will also depend on the applicable state law, which the Commissioner notes, can be adjusted by state courts and Legislatures in light of the facts presented by patient labeling."

43 Fed. Reg. 4214 (Jan. 31, 1978).

An examination of the record of the evidence presented at the trial of this case and reviewed by the Supreme Judicial Court on appeal rebuts Ortho's allegations that the Appellate Court "ma[de] up" peculiar characteristics of oral contraceptives without evidence "in the record or in the real world" (Pet. p. 5).

Contrary to Ortho's claim, the record contains ample evidence to support the lower court's conclusion that the oral contraceptive stands apart from other prescription drugs and requires a direct warning to the patient of the substantial risks affiliated with its use. (See *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. at 138.)

Evidence in the record to support this conclusion includes the following:

*Patient involvement*

Oral contraceptives are used for long periods of time by large numbers of women, who, for the most part are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception. (R. 80); 35 Fed. Reg. 9002 (1970).

*Limited participation by prescribing physician*

Mrs. MacDonald first received a prescription for birth control pills from her physician in 1973 and, thereafter, saw him for a yearly check-up, each time receiving a prescription for one year's supply of the pills (R. 144, 145).

The prescribed dosage is one tablet daily and the pills are available in bottles of 500 tablets (R. 56).

*Extensive Federal regulations*

Dating back to at least 1970, the FDA has published rules and regulations establishing labeling requirements for oral contraceptives (R. 79, 80, 81), 35 Fed. Reg. 9001, 9002, 9003 (1970).

*Substantial risks affiliated with its use*

A large number of adverse reactions were observed in patients (R. 56).

They are powerful drugs which can cause side effects. The most serious side effect is abnormal blood clotting which can be fatal (R. 57).

There is increased risk of thromboembolic disease, pulmonary embolism and cerebral vascular disease, associated with their use (R. 83, 84, 85).

People who use the pill are at a greater risk of thromboembolic disease, stroke being one of them, than the women who are not using the pill (R. 95).

Abnormal blood clotting and stroke are risks associated with the use of oral contraceptives (R. 101).

There is a positive association between the pill and stroke and with heart attacks and other diseases (R. 184).

The risk-factor for stroke for pill users as compared to non-users is as high as 20 times greater (R. 189).

No other drug has been written about as much in medical literature. (R. 298).

*Feasibility of direct warning*

Since 1970, the FDA has mandated a direct warning from the manufacturer to the purchaser of birth control pills (R. 80, 81).

In 1976, when Mrs. MacDonald suffered her stroke, oral contraceptives were the only prescription drug for which the FDA had mandated such a direct warnning (R. 286, 302, 303).

*Possibility that oral communications between physicians and consumers may be insufficient*

In determining the need for a direct warning, the FDA Commissioner concluded that

1. Many patients were not receiving the needed information in an organized, comprehensive, understandable and handy-for-future-reference form.

> 2. The necessary information for the safe and effective use of oral contraceptives is too complex to expect the patient to remember everything told her by the physician.
>
> The FDA was not provided assurance that persons for whom oral contraceptives are prescribed or dispensed were uniformly being provided the necessary information for safe and effective use of the drugs.
>
> Consumer spokesmen contended that there was ample evidence that physicians were not uniformly providing the information, and that when they do the patient cannot be expected to remember all of the details for a protracted period of time. (R. 80) 35 Fed. Reg. 9052 (1970).

Thus, it appears obvious that there is no basis for Ortho's contention that the State Court adopted a new rule of law on the basis of "fictive" findings of fact which Ortho was never allowed to test (Pet. p. 6).

* * *

The jury's award of $800,000.00 in damages to Mrs. MacDonald was intended as compensation to her for the permanent disability resulting from her stroke (R. 40, 41). The damage award was not punitive, nor is there anything in the record to suggest that the proceedings below were in any way discriminatory of Ortho or tended to make it a "scapegoat for public ire" as suggested. (Pet. p. 16, 17).

## CONCLUSION

Ortho has had its day(s) in the Massachusetts Courts. No substantial Federal question has been raised by it, which should invoke the reviewing power of this Court.

For all of the reasons set forth above, this Petition for a Writ of Certiorari to the Supreme Judicial Court of Massachusetts should be denied.

Respectfully submitted,

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